

REMARKS

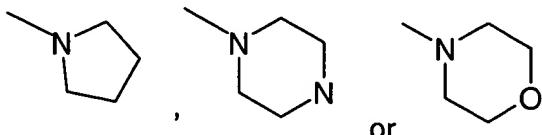
Reconsideration of the Office Action mailed March 31, 2004, (hereinafter "instant Office Action"), and withdrawal of the election requirement directed to claims 1-60, are respectfully requested.

In the instant Office Action, claims 1-60 are listed as pending and claims 1-60 are subject to restriction and/or election requirement. The Examiner alleges that the instant application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually and that moreover, each of these inventions contains a plurality of patentably distinct compounds. The Examiner has required restriction to one of the following inventions:

I. Claims 1-22, and 38-58, in part, drawn to compounds/compositions wherein the variable Q represents hydrogen thereof; the variables Q and X<sup>1</sup>, and two nitrogen atoms, are not



together to form the ring; the variable Y represents O or S; the variable W does not represent heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety, and the variable W is not substituted with heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety thereof; the variable X<sup>1</sup> does not represent heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety, and the variable X<sup>1</sup> is not substituted with heteroaryl or heterocycle (i.e., morpholine, piperidine, etc) moiety thereof, the variables R<sup>1</sup>, R<sup>2</sup>, and R<sup>3</sup> independently do not represent heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety, the variables R<sup>1</sup>, R<sup>2</sup>, and R<sup>3</sup> independently are not substituted with heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety; the variables R<sup>1</sup> and W together with their attached carbons do not form a 5- or 6-membered heterocyclyl ring thereof; R<sup>3</sup> and X<sup>1</sup> together with the nitrogen atom do not

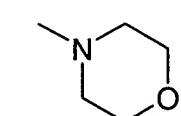
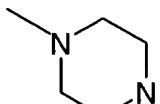
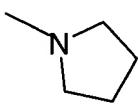


form a heterocycle ring , or thereof; classified in classes 514/548, numerous subclasses.

II. Claims 1-22, and 38-58, in part, drawn to compounds/compositions wherein the variable Q represents hydrogen thereof; the variables Q and X<sup>1</sup>, and two nitrogen atoms, are not



together to form the ring; the variable Y represents O or S; the variable W does not represent heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety, and the variable W is not substituted with heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety thereof; the variable X<sup>1</sup> does not represent heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety, and the variable X<sup>1</sup> is not substituted with heteroaryl or heterocycle (i.e., morpholine, piperidine, etc) moiety thereof, the variables R<sup>1</sup> and R<sup>2</sup> independently do not represent heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety, the variables R<sup>1</sup> and R<sup>2</sup> independently are not substituted with heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety; the variable R<sup>3</sup> represents heterocycle morpholine or piperazine thereof, the variables R<sup>1</sup> and W together with their attached carbons do not form a 5- or 6-membered heterocyclyl ring thereof; R<sup>3</sup> and X<sup>1</sup> together with the nitrogen atom do not form a heterocycle ring



or

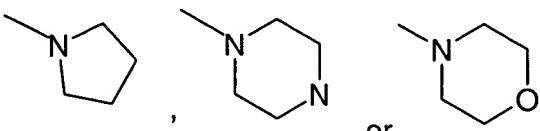
thereof; classified in classes 514/544, numerous subclasses.

III. Claims 1-22, and 38-58, in part, drawn to compounds/compositions wherein the variable Q represents hydrogen thereof; the variables Q and X<sup>1</sup>, and two nitrogen atoms, are not together



to form the ring; the variable Y represents O or S; the variable W does not represent heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety, and the variable W is not substituted with heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety thereof; the variable X<sup>1</sup> does not represent heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety, and the variable X<sup>1</sup> is not substituted with heteroaryl or heterocycle (i.e., morpholine, piperidine, etc) moiety thereof, the variables R<sup>1</sup> and R<sup>2</sup> independently do not represent heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety, the variables R<sup>1</sup> and R<sup>2</sup> independently are not substituted with heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety; the variable R<sup>3</sup> represents heterocycle piperidine or pyridine thereof, the variables R<sup>1</sup> and W together with their attached carbons do not form a 5- or 6-membered heterocyclyl ring

thereof;  $R^3$  and  $X^1$  together with the nitrogen atom do not form a heterocycle ring



or

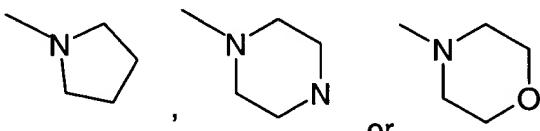
thereof; classified in classes 514/546, numerous

subclasses.

IV. Claims 1-22, and 38-58, in part, drawn to compounds/compositions wherein the variable  $Q$  represents hydrogen thereof; the variables  $Q$  and  $X^1$ , and two nitrogen atoms, are not together



to form the 1,2-diazepine ring; the variable  $Y$  represents O or S; the variable  $W$  does not represent heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety, and the variable  $W$  is not substituted with heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety thereof; the variable  $X^1$  does not represent heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety, and the variable  $X^1$  is not substituted with heteroaryl or heterocycle (i.e., morpholine, piperidine, etc) moiety thereof, the variables  $R^1$  and  $R^2$  independently do not represent heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety, the variables  $R^1$  and  $R^2$  independently are not substituted with heteroaryl or heterocycle (i.e. morpholine, piperidine, etc) moiety; the variable  $R^3$  represents heterocycle imidazole thereof; the variables  $R^1$  and  $W$  together with their attached carbons do not form a 5- or 6-membered heterocyclyl ring thereof;  $R^3$  and  $X^1$  together with the nitrogen atom do not form a heterocycle ring



or

thereof; classified in classes 514/548, numerous

subclasses.

V. Claims 1-22, and 38-58, in part, drawn to compounds/compositions of a compound of formula (I), receiving compounds of formula (I) not encompassed in Groups I-IV, classified in classes 514/544/546/548, numerous subclasses.

VI. Claims 23-28, drawn to methods of use (i.e. protein kinase inhibition) of a compound of formula (I), classified in classes 514, numerous subclasses.

VII. Claims 29-37, and 59-60 drawn to methods of use (i.e. treating ulcer or tumors) of a compound of formula (I), classified in classes 514, numerous subclasses.

Applicants provisionally elect Group I with traverse. The Examiner has requested the election of a single species and Applicants elect the species N-ethyl-N'-(6-nitro-1,3-benzothiazol-2-yl)urea which is Example 8 on page 70 of the instant specification, wherein W is NO<sub>2</sub>, R<sup>1</sup> is H, R<sup>2</sup> is H, Q is H, Y is O, R<sup>3</sup> is ethyl. Claims 1-6, 12, 14, 23-39, 50, and 57-60 read upon the provisionally elected species. The Examiner has invited Applicants may set forth a group of compounds which are so similar within the same inventive concept and reduction to practice. Applicants respectfully decline to set forth such a group.

The Examiner alleges on page 2 of the instant Office Action that the Markush group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. Proper restriction between independent and distinct inventions claimed in the same application requires that (1) the invention must be independent or distinct as claimed and (2) there must be a serious burden placed on the Examiner by not requiring restriction. If either criteria is not met, restriction is not proper.

With respect to the term “independent”, “independent” means that there is no disclosed relationship between the two or more subjects disclosed in a patent application. M.P.E.P. §802.01. The instant application is directed to novel compounds and their use as kinase inhibitors. Specifically, the invention relates to benzothiazole derivatives and their use in treating diseases. Applicants respectfully point out that the single inventive concept of all of the therapeutic agents listed in claims 1-60 is that they are useful as inhibitors of serine/threonine and tyrosine kinases. In particular, compounds of the instant invention are useful as inhibitors of tyrosine kinases important in hyperproliferative diseases. (see page 33, lines 19-21 of the specification). Thus, all of the aforementioned compounds fall within the inventive concept of the instant application. Further, all of the compounds share structural commonality of the benzothiazole. Therefore, the subjects of the instant application are not “independent” as determined by M.P.E.P. 802.01.

The term “distinct”, as defined in M.P.E.P. § 802.01, means two or more subjects as disclosed are capable of separate manufacture, use or sale as claimed, and are patentable over each other. In the instant application, the invention is directed to novel compounds and their use as kinase inhibitors or to treat diseases. One cannot use the instant compounds to treat diseases

without first synthesizing or manufacturing said compounds. Thus, Groups I-IV versus Groups V and VI-VII do not meet the criteria for “distinct” as defined in M.P.E.P. § 802.01.

Thus, Applicants respectfully submit that the instant invention does not meet the threshold of “two or more independent or distinct” inventions as required in 35 U.S.C. §121 and as such the restriction requirement is improper.

If the Examiner maintains the restriction requirement, the Examiner should at the very least group the claims as follows. Groups I, II, III and IV should be combined into one group. Groups VI and VII should be combined into one group.

With respect to the burden of the examination, M.P.E.P. §803 states:

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions.

Applicants respectfully request that Group I, classes 514/548, Group II, classes 514/544, Group III, classes 514/546 and Group IV, classes 514/548, be combined into a single group. Claims 1-22 and 38-58, in part, read upon Groups I-IV. These groups are directed to novel benzothiazole derivatives. These groups all share the class 514 and Groups I and IV also share class 548. Thus, Applicants submit that the Examiner could search and examine Groups I-IV without serious burden.

Applicants respectfully request that Group VI, class 514 and Group VII, class 514 be combined into a single group. Claims 23-28 read upon Group VI, and claims 29-37 and 59-60 read upon Group VI. Both groups share class 514 and are directed to methods of use of the novel benzothiazole derivatives. Thus, Applicants submit that the Examiner could search and examine Groups VI and VII without serious burden.

Based upon the foregoing, the restriction requirement should be withdrawn and all of the subject matter of claims 1-60 should be prosecuted together. Prompt and favorable action is earnestly solicited.

If the Examiner believes that there are any issues that could be resolved in a telephone conference, Applicants invite the Examiner to call Applicants' undersigned attorney.

Respectfully submitted,

Date: Apr. 1 30, 2004

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